

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IN2004/000142

International filing date (day/month/year)
20.05.2004

Priority date (day/month/year)
19.03.2004

International Patent Classification (IPC) or both national classification and IPC
C07H1/06, C07H5/02

Applicant
PHARMED MEDICARE PRIVATE LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-23
	No: Claims	24-25
Inventive step (IS)	Yes: Claims	1-23
	No: Claims	24-25
Industrial applicability (IA)	Yes: Claims	1-25
	No: Claims	

2. Citations and explanations
see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

D1: P.H. Fairclough et al. Carbohydrate Res. 40 (1975) 285-298

D2: US4380476

Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 24 and 25 is not new in the sense of Article 33(2) PCT.

The documents D1 and D2 disclose the synthesis and isolation of sucralose, thus claims 24 and 25 lack novelty since a product by process must be new and inventive. A product is not rendered novel merely by the fact that it is produced by a new process.

Inventive step

The present claims 1-23 meet the criteria of Article 33(1) PCT in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claims 1-23, and discloses the synthesis and isolation of sucralose

The subject-matter of claims 1-23 differs from this known subject matter in that a drying step or super critical extraction step as in claim 1 is included. Furthermore, a deacetylation of intermediates of chlorinated sucrose is performed before as well as after said drying step.

The problem to be solved by the present invention may therefore be regarded as the provision of further processes for the synthesis and isolation of sucralose.

The solution proposed in claims 1-23 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons.
It is not obvious for the skilled person to include a drying step as in claim 1 and to perform

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a deacetylation before as well as after said drying step. In D1 there is no incentive to do so.

ABSTRACT

Present invention relates to disclosure of application of some innovative techniques useful for substantially improving process efficiency of production of chlorinated sucrose including their intermediates and derivatives. Application of mild methods of drying has been made for recovery of chlorinated sucrose or their intermediates and derivatives, in substantially pure form or with other solid chemical impurities, obtained at various stages in the process of production of chlorinated sucrose. Mild methods of drying included agitated thin film drying, spray drying, freeze drying and super critical extraction. Use of alkoxides has been introduced for deacylation instead of alkali hydroxides or alkaline earth hydroxides. Deacylation has been shown to be effective both, either before or after drying of the reaction mixture. Extraction and purification of desired products i.e. of chlorinated sucrose or its intermediates or derivatives, from dried solid mixtures could be achieved by using appropriate extraction method, including but not limited to solvent extraction and super critical extraction. Further purification of such extracts can be done by crystallization or direct drying under mild conditions.